SUMMARY OF THE ON-SITE ASSESSMENT COMMITTEE MEETING OCTOBER 31, 2000

The On-site Assessment Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Tuesday, October 31, 2000 at 1:30 p.m. Pacific Standard Time (PST) as part of the Sixth NELAC Interim Meeting (NELAC 6i) in Las Vegas, NV. The meeting was led by its chair, Mr. William Ingersoll of the U.S. Navy. A list of action items is given in Attachment A. A list of participants is given in Attachment B. An updated summary of the committee's proposed changes to Chapter 3 are given in Attachment C. *The purpose of the meeting was to address items of importance as outlined in the detailed agenda distributed in meeting packets.*

INTRODUCTION

Following an explanation of the ground rules by Mr. Michael Beard, the meeting's facilitator, Mr. Ingersoll called the meeting to order with an introduction of committee members and a review of the agenda. The committee then proceeded with their agenda items.

APPENDIX A (BASIC NELAC ASSESSOR TRAINING)

Mr. Ingersoll explained that it has come to the committee's attention that there are inconsistencies in the performance of laboratory assessments. Although it is outside the scope of the On-site Assessment Committee to evaluate assessors, it is within the scope of the committee to establish standards for the proper training of assessors. To that end, the committee has prepared three appendices to address assessor training issues. Appendix A consists of an outline for basic NELAC assessor training. A basic NELAC assessor training course was prepared by a private contractor and offered as a pilot course early in 2000. Since the prepared course was considered by some people to be too prescriptive, the committee prepared an appendix in outline format that establishes criteria that training vendors must meet. The committee noted that they have proposed changes to Chapter 3 of the NELAC Standard to remove specified durations for the training course elements and to reference the appendices. Discussion from the floor was mixed. Although one commenter questioned the value of a mock inspection and noted that NELAC assessors are supposed to have received initial training by their accrediting authority, several commenters suggested expanding the mock inspection to include report writing. It was suggested that the report serves a purpose for the individuals writing the report as well as the individuals reading the report. There were several references to the use of mock inspections in the Cincinnati drinking water course. The committee noted that they have received anecdotal evidence of assessor inconsistency. The committee also noted that although NELAC assessors are experienced assessors, they come from a variety of disciplines. In response to a question of how a training course would be assessed to the appendix, it was suggested that the committee include specific goals for the course as are included in Appendix B-1, which addresses technical training. There was some discussion of what is appropriately included in the basic training appendix and what should be included in technical training appendices. Several commenters suggested that Appendix A should include some sort of specified or recommended duration, at least for interactive activities such as the mock inspection or report-writing exercises, and that the appendix include references to Chapter 5. It

was noted that there is an expectation that lead assessors are better trained and in a decision-making position on the assessment team. The committee was urged to consider the impact of lead assessor designation with reference to two International Standardization Organization (ISO) documents (ISO 10000 and ISO 19010). There was considerable discussion of the detection of laboratory misconduct with emphasis on the fact that NELAC is not a policing organization. A distinction was made between sloppy error and intentional misconduct. It was noted that data auditing at the level of the original raw data is the best indicator of both sloppy error and laboratory misconduct. A commenter representing a national laboratory suggested that errors are most likely to occur in the areas of data interpretation, data management, and data handling and recommended that these areas be included in the basic training course. Commenters noted that a deficiency is only a deficiency if it can be couched in the language of the NELAC Standard and requested that the committee strike references to items that are not addressed in the NELAC Standard, such as cleanliness. In response, other commenters cited sections of the NELAC Standard that were expressed in a more colloquial fashion in the outline and suggested that the outline only needs wordsmithing. Commenters noted that some level of specialized technical training is necessary and suggested that the basic course include break-out sessions for particular disciplines. There was considerable discussion of whether there is a market for the course and of how quickly the private sector will rise to the occasion in offering the training course. Committee members noted that the approved outline must be on record before vendors will offer the course. There was some discussion of smaller state programs and of third-party assessors. It was noted that references to reviewing previous on-site assessment reports should be broadened to include assessments performed by other organizations and the resulting corrective action reports. It was also noted that such a review of previous assessment reports is the mechanism by which corporate management may be implicated in conspiracy to commit misconduct if the review indicates that management knew about deficiencies and did nothing to correct them.

QUALITY SYSTEMS ASSESSMENT CHECKLIST UPDATE

Mr. Ingersoll acknowledged that Chapter 5 will be revised to incorporate ISO 17025 and introduced Mr. Charles Dyer to address the committee's Quality Systems Assessment Checklist. Mr. Dyer explained that the checklist has been revised to incorporate changes made to the 2000 Quality Systems standard. The checklist must be reviewed by the On-site Assessment Committee before it can be submitted for posting on the NELAC Website. It will be revised again when the Quality Systems Standard is revised. The Quality Systems checklist is the only NELAC assessment checklist in existence at this time. However, each accrediting authority has its own method or technology-specific assessment checklists.

APPENDIX B-1 (STANDARDS FOR TECHNICAL TRAINING COURSES FOR ASSESSORS) AND APPENDIX B-2 (STANDARDS FOR CRITICAL PERFORMANCE ELEMENTS OF TEST METHODS)

Mr. Jack Hall introduced Appendices B-1 and B-2. He explained that the committee has come to the realization that there are existing technical training courses in the environmental marketplace that may be appropriate for NELAC assessors. Appendices B-1 and B-2 have been developed to set the criteria that training courses must meet. The two appendices were opened together for discussion from the floor. It was suggested that an examination be included in technical training courses. The courses are

intended to be technology-specific. It was also suggested that a mock laboratory inspection and a performance-based measurement system (PBMS) section be included in technical training courses. A commenter suggested that it is not enough to review instrument calibration. An analyst's knowledge of what is happening to the instrument to affect calibration must also be reviewed. It was also suggested that Appendix B-1 should be more specific as to the technical knowledge prerequisite for technical courses. It was suggested that the courses include a pretest to evaluate threshold knowledge. A regulatory commenter noted that Appendix B-1 cannot be audited as written and recommended that the appendix be rewritten in standard language. The commenter noted that ISO 10000 has a great deal of information on credentialing of auditors. It was suggested that developing a bank of examination questions would be one way to maintain uniformity between course offerings. There was discussion of the data handling and data management issues mentioned in discussion of Appendix A and of verification of qualitative identification. In discussion of data interpretation it was noted that assessors must be trained to verify that analysts are capable of going beyond cook book operation of their instruments. It was suggested that the committee should include some moderating language to set a threshold of the level of detail that must be examined. It was noted that the critical elements for technical training do not include items that are not specific to a given technology (sample receipt, data reporting, archiving, etc.) The committee responded that these elements would be covered in the basic training course's review of the Chapter 5 checklist. Commenters suggested that the Quality Systems sections must be properly referenced in Appendix A in order to assure that training vendors develop curricula that adequately cover these issues. It was suggested that Appendices B-1 and B-2 should be expanded into a format similar to Appendix A. In response the committee urged stakeholders to submit in writing proposed language to accomplish this task.

DISCUSSION OF PROPOSED CHANGES TO CHAPTER 3

Mr. Ingersoll explained that several of the committee's proposed changes had not been made in time to be included in printed meeting materials. He reviewed proposed changes line by line and opened the changes to discussion from the floor. There was considerable discussion from the floor of assessor training. The committee noted that accrediting authorities are responsible for the training of their assessors. Each accrediting authority must make an independent decision about each training course to assure that their assessors are adequately trained. This issue proved to be disturbing for several members of the audience. Several commenters noted that it had been their understanding that the committee's approach to training was to be a stopgap measure only until there were National Environmental Laboratory Accreditation Program (NELAP)-approved courses for assessors. They questioned how new accrediting authorities can be expected to evaluate the quality of training courses when they have not yet been trained, themselves. They also questioned what would happen to reciprocity if one accrediting authority approved a training course and other accrediting authorities did not approve the course. It was suggested that there would be some vehicle for the accrediting authorities to communicate with each other, such as the Accrediting Authority Workgroup teleconferences. The committee reiterated that NELAC/NELAP does not have the authority to approve training courses and that the committee's charge is to develop a standard for training. There was some discussion of the timeline for assessor training. Committee members noted that training courses are not yet available and that references to the timeline can be changed when the program is more mature. A commenter from the NELAC Accrediting Authority Committee noted that his

committee has been wrestling with the issues of length of assessments and consistency of assessments. While acknowledging that the On-site Assessment Committee cannot be prescriptive in its language, he suggested that they include language in Chapter 3 to provide prudent guidelines as to the length of assessments. This would set the stage so that all parties would know what is expected of an assessment and would improve consistency. In response the On-site Assessment Committee requested that the commenter provide suggested language. Other commenters noted that the length of the assessment is largely dependent on the laboratory and suggested that professional judgement may determine the length of the assessment.

CONCLUSION

Since the committee's allotted meeting time had expired, Mr. Ingersoll thanked participants for their input. He adjourned the meeting shortly after 5:00 p.m. PST.

Attachment A

ACTION ITEMS
ON-SITE ASSESSMENT COMMITTEE MEETING
OCTOBER 31, 2000

Item No.	Action	Date to be Completed
1.	Committee will coordinate with accrediting authorities and Transition Committee to investigate uniformity and consistency of on-site assessments.	03/19/00
2.	Committee will incorporate proposed changes into training appendices in order to develop an assessor training standard.	03/19/00
3.	Committee will explore feedback mechanisms to appraise on-site assessments.	03/19/00
4.	Committee will consider maximum lagtime allowed between NELAP recognition of an accrediting authority and completion of assessor training by the accrediting authority's assessors.	03/19/00
5.	Committee will incorporate proposed changes into Chapter 3 of the NELAC Standard.	03/19/00

Attachment B

PARTICIPANTS
ON-SITE ASSESSMENT COMMITTEE MEETING
OCTOBER 31, 2000

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PROPOSED CHANGES TO CHAPTER 3
ON-SITE ASSESSMENT COMMITTEE MEETING
OCTOBER 31, 2000

Section 3.2 -ON-SITE ASSESSMENT PERSONNEL - The committee agreed on the following changes to this section:

C **Section 3.2.1 - Basic Qualifications**

Each assessor must satisfactorily complete a training program approved by the accrediting authority responsible for on-site assessments. Each accrediting authority shall be responsible for ensuring that the training course used to train its assessors meets the NELAC standards. This program shall include training on the NELAC standards; on how to conduct a laboratory assessment; on the technology and requirements appropriate for each particular field of testing for which they are conducting laboratory on-site assessments; and participation in at least four actual NELAC on-site assessments under the supervision of a qualified assessor. Training in the NELAC standards and on how to conduct a laboratory assessment shall be satisfied by successful completion of NELAC Basic Assessor Training. Assessors must take annual refresher/update training as defined in Section 3.2.3. Assessors employed by an accrediting authority (either directly or as a third party) when the accrediting authority is granted NELAP recognition (See Section 6.7) are exempt from the requirement to undergo training with a qualified assessor, provided they have previously conducted four assessments and been judged proficient by the accrediting authority.

All assessors must complete NELAC Basic Assessor Training within two years of becoming an assessor. Persons serving as lead assessors shall have completed the NELAC Basic Assessor Training before serving as lead assessor. Assessors must complete the applicable technical training requirements within four years after the NELAC-specified technical training is offered.

C **Section 3.2.3 - Training**

The National Environmental Laboratory Accreditation Conference (NELAC) specifies the minimum level of education and training for assessors, including refresher/update training. The NELAC also develops standards for training requirements. The assessor training program is implemented by either accrediting authorities, assessor bodies, or other entities. All assessor training programs must meet the standards defined in this Chapter.

The purpose of the basic assessor training is to familiarize the assessor with the NELAC standards and the skills and techniques associated with the laboratory assessment. The basic assessor training course shall encompass all the material described in Appendix A.

"NELAC Basic Assessor Training" text box - Delete text box and its contents.

The specific training associated with the NELAC standards is required and must be successfully completed. All assessor candidates must pass the written examination.

In addition to the basic NELAC assessor training, each assessor must successfully complete training in at least one technical discipline.

The technical training program is defined in Appendix B. The purpose of the technical training is to ensure consistency of knowledge and techniques among the NELAC assessors. The technical training assumes a level of basic knowledge of the subject and concentrates on the elements of the technology or methods that are key to properly assure laboratory competency to deliver data of known and documented quality. The technical training program consists of the following:

NELAC Technical Training for Assessors" text box - Delete all parenthetical references to duration of training for each technical discipline. Retain text box and all other contents.

The purpose for requiring refresher/update training for all assessors is to ensure that the assessors are aware of changes to the standards and/or approved analytical methodology as they occur and to enhance and improve skills associated with assessment. Assessors are expected to maintain proficiency on an on-going basis. Assessors must complete refresher/update training annually. Initially, the refresher/update training is conceptualized as follows:

"NELAC Refresher/Update Training for Assessors" text box - Delete the words "Day 1." Retain text box and all other contents.

Section 3.4 - PRE-ASSESSMENT PROCEDURES - The committee agreed on the following changes to this section:

- **Section 3.4.1 - Assessment Planning** - A good assessment begins with planning, which starts before the assessment team visits the laboratory. Planning is the means by which the lead assessor identifies all the required activities to be completed during the assessment process. Planning includes conducting a thorough review of NELAP and/or State records pertaining to the laboratory to be inspected. This saves time because familiarity with the operation, history, and compliance status of the laboratory increases the efficiency and focus of an on-site visit.

  Pre-assessment activities include: determining the scope of the assessment; reviewing NELAP/State information; providing advance notification of the assessment to the laboratory, when appropriate; obtaining any security clearances and determining any special safety procedures which may be necessary; coordinating the assessment team; and gathering assessment documents. Section 3.4.5 discusses Confidential Business Information (CBI) issues.

- **Section 3.4.3 - Information Collection and Review**

Prior to initiating an on-site assessment, the assessment team shall make determinations as to which laboratory records they wish to review prior to the actual site visit. These records, from the files of the accrediting authority, the national laboratory accreditation database, or the laboratory itself include, but are not limited to:

a) Copies of previous assessment reports and proficiency testing sample results;

b) General laboratory information such as laboratory submitted self-assessment forms, SOPs and Quality Manual(s);

c) Official laboratory communications and associated records with appropriate accrediting authority staff;

d) Available documents from recipients of reports from the laboratory;

e) The laboratory's application for accreditation;

f) The existing program regulations (federal and state), and

g) The most recently approved or in use laboratory methods for which the laboratory has requested or maintains accreditation.

Section 3.5 - ASSESSMENT PROCEDURES - The committee agreed on the following changes to this section:

C **Section 3.5.1 - Length of Assessment**

The length of an on-site assessment depends upon a number of factors such as the scope of accreditation, the number of assessors available, the size of the laboratory, the number of problems encountered during the assessment, and the cooperativeness of the laboratory staff. The accrediting authority must assign an adequate number of assessors to complete the assessment within a reasonable period of time. Assessors must strike a balance between thoroughness and practicality, but in all cases must determine to what extent the laboratories' operations meet NELAC standards.

C **Section 3.5.2 - Opening Conference**

Arrival at the facility for routine NELAC assessments occurs during established working hours unless special arrangements are made with the laboratory.

A laboratory's refusal to admit the assessment team for assessment team for assessment results in an automatic failure of the laboratory to receive accreditation or loss of an existing accreditation by the laboratory, unless there are extenuating circumstances that are accepted and documented by the accrediting authority. The assessment team leader must notify the accrediting authority as soon as possible after refusal of entry.

An opening conference must be conducted and shall address the following topics:

h) the purpose of the assessment;

b) the identification of the assessment team;

c) the primary areas that will be examined;

d) any pertinent records and operating procedures to be examined during the assessment and the names of the individuals in the laboratory responsible for providing the assessment team with the necessary documentation;

e) the roles and responsibilities of key managers and staff in the laboratory;

f) the procedures related to Confidential Business Information;

g) any special safety procedures that the laboratory may think necessary for the protection of the assessment team while in certain parts of the facility (under no circumstance is an assessment team required or even allowed to sign any waiver of responsibility on the part of the laboratory for injuries incurred by a team member during an inspection to gain access to the facility);

h) the standards that will be used by the assessors in judging the adequacy of the laboratory operation;

i) the confirmation of the tentative time for the exit conference;

j) the presentation of the assessment appraisal form to the responsible laboratory official for submittal to the accrediting authority; and

k) the discussion of any questions the laboratory may have about the assessment process.